REMARKS

This communication is in response to the Nonfinal Office Action dated August 22, 2007, in which the drawings are objected to as failing to comply with 37 CFR 1.84(p)(4), claims 2 & 17 are objected to because of informalities, claims 1-6, 8, 10-11, 15-20, 23, 29-31, 40, 41, 45, 46 & 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly '463 et al. (US Patent Application No. 200310004463 A1) and further in view of Hamadeh '188 et al. (US Patent Application No. 200410088188 A1), claims 7, 21, 26, 27, 28, 37, 42, 47 & 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly '463 et al. (US Patent Application No. 200310004463 A1) and in view of Hamadeh 'l88 et al. (US Patent Application No. 200410088188 A1) and further in view of Critchlow '930 et al. (US Patent No. 6,520,930), claims 9, 12-13, 22, 24, 35, 36, 38, 43, 49-51, 54-56, 58, 61-63, 65-68, 70-77, 79 & 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly '463 et al. (US Patent Application No. 200310004463 A1) and in view of Hamadeh '188 et al. (US Patent Application No. 200410088188 A1) and further in view of Tamaki '1989 (Tamaki, et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989), claims 33 & 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly '463 et al. (US Patent Application No. 200310004463 A1) and in view of Hamadeh '188 et al. (US Patent Application No. 200410088188 A1), in view of Critchlow '930 et al. (US Patent No. 6,520,930 B2) and further in view of Tamaki 'l989 (Tamaki, et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989), claims 14, 25, 34, 39, 44, 52, 53, 59, 60, 64, 69 & 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly '463 et al.

(US Patent Application No. 200310004463 A1), in view of Hamadeh '188 et al. (US Patent Application No. 200410088188 A1), in view of Kroll '869 et al. (US Patent Application No. 20050288869 A1) and further in view of Tamaki '1989 (Tamaki, et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989), claims 81-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly '463 et al. (US Patent Application No. 200310004463 A1), in view of Hamadeh 'l88 et al. (US Patent Application No. 2004/0088188 A1), in view of Kroll '869 et al. (US Patent Application No. 2005/0288869 A1), and further in view of Tamaki '1989 (Tamaki, et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989), claims 84 & 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly '463 et al. (US Patent Application No. 200310004463 A1), in view of Hamadeh '188 et al. (US Patent Application No. 2004/0088188 A1), and further in view of Tamaki '1989 (Tamaki, et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989).

Objection to drawings

Per FIG. 1: The "drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "130" has been used to designate both living subject and physiological monitors. Also, reference character "120" has been used to designate both cyclotron and lead-shielded lines."

Is response, Applicant submits replacement sheet for FIG. 1 in which the connecting line between label 130 is extended closer to the subject and in which the

"line" between "dispensing station" 106 and "injector" 124 is changed to be numbered as 120.

Per FIG. 5: "The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 500."

In response, label "500" is added to FIG. 5.

Objection to claims 2 & 17

Claims 2 & 17 are objected to because of informalities.

Claims 2 & 17 are amended to remedy misspelling of "further."

Rejection of claims 1-6, 8, 10-11, 15-20, 23, 29-31, 40, 41, 45, 46 & 48 under 35 U.S.C. 103(a)

Claims 1-6, 8, 10-11, 15-20, 23, 29-31, 40, 41, 45, 46 & 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly '463 et al. (US Patent Application No. 20030004463 A1) and further in view of Hamadeh '188 et al. (US Patent Application No. 20040088188 A1).

Per claim 1:

Absent Elements in the References:

The Office Action asserts that "a local area network operably coupled to at least one positron emission tomography imaging system…" is disclosed by figure 1A, element 40, page 1 paragraph 4 and page 6 paragraph 61 of Reilly '463. However, element 40 in figure 1A is "a source 40 of a pharmaceutical to be injected into a patient" (Reilly '463 paragraph 49) which is not disclosure of either "a local area network" or "at least one positron emission tomography imaging system."

Furthermore, paragraph 4 of Reilly '463 does not provide the required disclosure of "a local area network operably coupled to at least one positron emission tomography imaging system…" Paragraph 4 follows below for the convenience of the Examiner:

> [0004] Examples of use of a radiopharmaceutical include positron emission tomography (PET) and single-photon emission computerized tomography (SPECT), which are noninvasive, three-dimensional, imaging procedures that provide information regarding physiological and biochemical processes in patients. The first step in producing PET images or SPECT images of, for example, the brain or another organ, is to inject the patient with a dose of the radiopharmaceutical. The radiopharmaceutical is generally a radioactive substance that can be absorbed by certain cells in the brain or other organ, concentrating it there. For example, fluorodeoxyglucose (FDG) is a normal molecule of glucose, the basic energy fuel of cells, to which is attached a radionuclide or radioactive fluor. The radionuclide is produced in a cyclotron equipped with a unit to synthesize the FDG molecule.

Paragraph 4 discloses the "imaging procedure" of "positron emission tomography (PET)." However, that is not disclosure of "at least one positron emission tomography imaging system" as required by claim 1.

In addition, paragraph 61 of Reilly '463 does not provide the required disclosure of "a local area network operably coupled to at least one positron emission tomography imaging system…" Paragraph 61 follows below for the convenience of the Examiner:

> [0061] In that regard, all adjustments of control 38 were made before the radiopharmaceutical was drawn into fluid delivery set 15. Control 38 can also be adjusted remotely or automatically (for example, via electronic/computer control) in, for example, cases when some pharmaceutical is within

> fluid delivery set 15 (for example, in a second or subsequent procedure in a case in which fluid delivery set 15 is used for multiple deliveries/injections) to prevent exposure of administering personnel. Other types of valve systems or assemblies, for example, a manifold system, can be used to affect the control of valve assembly 16.

Paragraph 4 of Reilly '463 discloses that "[c]ontrol 38 can also be adjusted remotely or automatically (for example, via electronic/computer control)." However, this disclosure is a far cry from the language of claim 1: "a local area network operably coupled to at least one positron emission tomography imaging system…"

Nowhere in Reilly '463 is "at least one positron emission tomography imaging system" disclosed. Much less does Reilly '463 disclose "a local area network operably coupled to at least one positron emission tomography imaging system…" Reilly '463 is completely void of any such disclosure. Thus, Applicant requests withdrawal of the rejection of claim 1 under 35 U.S.C. 103(a).

In addition, claim 1 requires "control system" .. "operable to receive status information from, and send commands to, the at least one positron emission tomography imaging system." The Office Action cites paragraph 61 of Reilly '463 as disclosure of "a control system operably coupled to the local area network and operable to receive status information from, and send commands to, the at least one positron emission tomography imaging system and the dispensing station. However, paragraph 61 of Reilly '463 does not provide the required disclosure. Paragraph 61 follows below for the convenience of the Examiner:

> [0061] In that regard, all adjustments of control 38 were made before the radiopharmaceutical was drawn into fluid delivery set 15. Control 38 can also be adjusted remotely or automatically (for example, via electronic/computer control)

> in. for example. cases when some pharmaceutical is within fluid delivery set 15 (for example, in a second or subsequent procedure in a case in which fluid delivery set 15 is used for multiple deliveries/injections) to prevent exposure of administering personnel. Other types of valve systems or assemblies, for example, a manifold system, can be used to affect the control of valve assembly 16.

Please note that paragraph 61 does not disclose "a control system operably coupled to the local area network" or a "control system" .. "operable to receive status information from, and send commands to, the at least one positron emission tomography imaging system." Reilly '463 is completely void of any such disclosure. Thus, Applicant requests withdrawal of the rejection of claim 1 under 35 U.S.C. 103(a).

Claim 1 also requires "a control system operably coupled to the local area network." However, neither Reilly '463 nor Hamedeh '188 disclose the "coupled" aspect between the "control system" and the "local area network."

Reasoning to Combine: In regards to the reasoning to combine Reilly '463 and Hamedeh '188, the Office Action states that "It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly '463 and Hamedeh '188 in order to maintain data integrity by having a network." While Hamedeh '188 does state that:

> "The workflow described above can also be helpful in maintaining data integrity by limiting data entry to the HIS 12, and preventing manual updates at the workstation 14. Because data is entered at only one place, no mismatch in data can occur between the HIS 12 and the workstation 14." (Hamedeh '188 paragraph 32)

However, Reilly '463 does not disclose that "data integrity" is a problem. Thus the reasoning to combine Reilly '463 and Hamedeh '188 does not seem complete.

Surely, Hamedeh '188 does improve "data integrity" but would a person necessarily combine Hamedeh '188 with all other inventions, even when the other inventions do not resolve or leave outstanding, a problem with data integrity. More specifically, Applicant respectfully asks whether a person of ordinary skill in the art would necessarily combine Hamedeh '188 with Reilly '463 even when Reilly '463 does not resolve or leave outstanding, a problem with data integrity ?

In particular, the reasoning of the Office Action merely recites benefits of "data integrity" with no reasoning as to why the recited benefits are particularly useful or beneficial to the invention of Reilly '463. A person of ordinary skill in the art would see no relationship between Hamedeh '188 with Reilly '463. Thus, the requirement in the KSR v. Teleflex case of a reason to combine the references is absent in the Office Action.

Applicant respectfully suggests that a person of ordinary skill in the art would not combine Hamedeh '188 with Reilly '463 because there is no reason to combine Hamedeh '188 with Reilly '463 because a person of ordinary skill in the art would see no relationship between Hamedeh '188 with Reilly '463.

Hindsight bias: While the Office Action asserts that there is a reason to combine Hamedeh '188 with Reilly '463, on the contrary, Applicant respectfully suggests that the combination of Hamedeh '188 and Reilly '463 is disapproved by the U.S. Supreme Court. In the KSR v. Teleflex case, the U.S. Supreme Court stated that:

> A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. See Graham, 383 U. S., at 36 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts 'to "'guard against slipping into the use of hindsight'" (quoting Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co., 332 F. 2d 406,412 (CA6 1964))) [KSR Int'l Co. v.

Teleflex Inc., 550 U.S. ___ (2007)].

The KSR decision also states that "but to judge Asano against Engelgau would be to engage in the very hindsight bias Teleflex rightly urges must be avoided." [Emphasis added.] The Court stated that hindsight bias must be avoided.

Yet, the search record shows that indeed, hindsight bias was at least a factor in the search performed in support of the Office Action. The "Examiner's Strategy and Results" dated Aug. 16, 2007, keywords from claim 1 were used to search:

	524	46	(position same emission same tomography) and (LAN or (local adj area adj network))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO	OR	ON	2007/08/16 13:05

Thus, the searches have been affected by impermissible hindsight bias and do not comport with the case law on obviousness in KSR Int'l Co. v. Teleflex Inc.

As MPEP 2141.01 instructs:

> "It is difficult but necessary that the decision maker forget what he or she has been taught . . . about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

Yet, in the searches conducted in support of this Office Action, the searches do not show that "what he or she has been taught . . . about the claimed invention" have been forgotten. On the contrary, the searches show that the language of the independent claims was a primary basis for the search. Thus, the obviousness

rejections of claims 1-6, 8, 10-11, 15-20, 23, 29-31, 40, 41, 45, 46 & 48 have been impermissibly affected by hindsight.

Again, the MPEP provides in section 2142 that:

> "The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art."

The case at hand shows how easily impermissible hindsight can be introduced into the examination process, in which the language of the independent claims was a primary basis for the search

The MPEP also provides that:

> Applicants may argue that the examiner's conclusion of obviousness is based on improper hindsight reasoning. However, "[a]ny judgement on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." In re McLaughlin 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971).

In the Office Action dated August 22, 2007, the rejections of claims 1-6, 8, 10-11, 15-20, 23, 29-31, 40, 41, 45, 46 & 48 are not proper because the judgment on obviousness for claims 1-6, 8, 10-11, 15-20, 23, 29-31, 40, 41, 45, 46 & 48 does "include knowledge gleaned only from applicant's disclosure."

Thus, Applicants respectfully submit that the obviousness rejection of claims 1-6, 8, 10-11, 15-20, 23, 29-31, 40, 41, 45, 46 & 48 was improper, and that claims 1-6, 8, 10-11, 15-20, 23, 29-31, 40, 41, 45, 46 & 48 are allowable. Applicant requests

withdrawal of the rejection of claims 1-6, 8, 10-11, 15-20, 23, 29-31, 40, 41, 45, 46 & 48 under 35 U.S.C. 103(a).

Prima facie case of obviousness: To establish a prima facie case of obviousness, the Supreme Court has articulated a four-prong test for determining obviousness:

> (A) Determining the scope and contents of the prior art;
> (B) Ascertaining the differences between the prior art and the claims in issue;
> (C) Resolving the level of ordinary skill in the pertinent art; and
> (D) Evaluating evidence of secondary considerations.

See KSR Int'l Co. v. Teleflex Inc., 550 U.S. ___ (2007), citing Graham v. John Deere, 383 U.S. 1, 148 USPQ 459 (1966).

The rejections of claims 1-6, 8, 10-11, 15-20, 23, 29-31, 40, 41, 45, 46 & 48 under 35 U.S.C. 103(a) do not discuss or "[r]esolve the level of ordinary skill in the pertinent art." As a result, a prima facie case of obvious of claims 1-6, 8, 10-11, 15-20, 23, 29-31, 40, 41, 45, 46 & 48 under 35 U.S.C. 103(a) was not presented in the Office Action. Applicant requests that the rejections of claims 1-6, 8, 10-11, 15-20, 23, 29-31, 40, 41, 45, 46 & 48 under 35 U.S.C. 103(a) be withdrawn.

Per claim 2: The Office Action asserts that paragraph 72 of Reilly '463 teaches "a quality control unit to monitor the radionuclic and chemical purity of the radiopharmaceutical…" However, Reilly '463 in paragraph 72 discloses matter that is lacking in disclosure of all aspects of the "quality control unit" and "chemical purity" Paragraph 72 is reproduced below for the convenience of the Examiner:

> FIGS. 5A through 5D illustrate several other embodiments of the present invention for providing dose calibration generally in real time. In FIG. 5A, a pressurizing device 520 (for

> example, a syringe in communication with a powered injector) and a radiopharmaceutical source 540 are positioned within a dose calibrator 550. In FIG. 5B, radiopharmaceutical source 540 is placed in a dose calibrator 550', while pressurizing device 520 is placed in a shielded enclosure 560. In the embodiment of FIGS. 5C and 5D, radiation level detectors are placed in operative connection with flow lines (for example, tubing). In FIG. 5C, a radiation detector 570 is placed in line between radiopharmaceutical source 540 (enclosed within a shielded container 580) and pressurizing device 520 (enclosed within a shielded container 590). In FIG. 5D, a radiation detector 570' is placed in line with the exit of pressurizing device 520. In general, the flow rate through the line in operative connection with radiation detector 570 or 570' is known. The radiation level of a particular dose is thus easily measured using radiation detectors 570 and/or 570'.

Please note that paragraph 72 of Reilly '463 does not disclose the aspects of the "quality control unit" and "chemical purity." Reilly '463 is completely void of any such disclosure. Thus, Applicant requests withdrawal of the rejection of claim 2 under 35 U.S.C. 103(a).

Per claim 3: The Office Action asserts that FIG. 1A of Reilly '463 discloses claim 3. However, Reilly '463 does not disclose that "the local area network is further operably coupled to a radioisotope producer." Thus, applicant requests that the rejection of claim 3 under 35 U.S.C. 103(a) be withdrawn.

Per claim 5: The Office Action asserts that "the radioisotope producer further comprises a linear accelerator" is a "design choice." However, in re Chu (66 F.3d 292, 298-99, 36 USPQ2d 1089, 1094-95 (Fed. Cir. 1995)) requires a teaching in the prior art for assertions of "design choice." In re Chu stated:

> From the totality of the record, we hold that placement of the SCR catalyst within the bag retainer would not have been merely a matter of "design choice." First, there is no teaching or suggestion in the prior art that would lead one of ordinary skill in the art to modify the Szymanski structure to place the SCR catalyst within a bag retainer as opposed to between two filter bags as disclosed in Szymanski.

In the Office Action, no citation or recitation of any prior art reference is made in the assertion of "design choice." Therefore, the rejection of claim 5 does not comport with federal court case precedent. Thus, applicant requests that the rejection of claim 5 under 35 U.S.C. 103(a) be withdrawn.

In addition, in the rejection of claim 5, the Office Action asserts that "a cyclotron and linear accelerator perform similar functions." However, "a cyclotron and linear accelerator" do not perform exactly the same function, thus there are situations in which a cyclotron will not work in the same manner as a linear accelerator. For this reason, claim 4 of the present patent application claims "a cyclotron" and claim 5 claims "a linear accelerator." These different claims have different functions, according to the language of the claims. Thus, claims 4 and 5 cannot be trivialized so easily as the Office Action attempts by characterizing the difference as a "design choice." As a result, Applicants request that the rejection of claim 5 under 35 U.S.C. 103(a) be withdrawn.

Per claim 11: The Office Action asserts that paragraph 33 of Hamadeh '188 teaches "a plurality of positron emission tomography imaging systems." However, Hamadeh '188 in paragraph 33 discloses "the imaging equipment 18 can provide **any number of imaging modalities** including x-ray, MRT, PET, ultrasound, or other imaging processes." [Emphasis added.] The "imaging equipment" is singular and

may include "any number of modalities" but paragraph 33 of Hamadeh '188 provides no disclosure of a plurality of "imaging equipment" in which each "imaging equipment" is of the same modality, such as "positron emission tomography imaging systems" as required by claim 11.

The plurality of modalities disclosed in Hamadeh '188 is not disclosure of the "plurality of positron emission tomography imaging systems." Thus at least this one particular element of claim 11 is not taught by the references. Therefore, applicant requests that the rejection of claim 11 under 35 U.S.C. 103(a) be withdrawn.

Per claim 15: The Office Action asserts that paragraph 61 of Reilly '463 teaches "the control system further comprises a computer system." However, Reilly '463 in paragraph 61 discloses "[c]ontrol 38 can also be adjusted remotely or automatically (for example, via electronic/computer control)…" [Emphasis added.]

Reilly '463 is very clear is in stating that "control 38" is adjusted by another device, that other device being a electronic/computer. There is no reason to assume that "control 38" of Reilly '463 is a computer or includes a computer. Thus at least this one particular element is not taught by the references. Therefore, applicant requests that the rejection of claim 15 under 35 U.S.C. 103(a) be withdrawn.

Per claim 16: The Office Action asserts that paragraph 10 of Reilly '463 teaches "a chemical synthesizer … to receive the radioisotope, and to produce a radiotracer." However, Reilly '463 in paragraph 10 discloses matter that is lacking in disclosure of all aspects of the "chemical synthesizer …" Paragraph 10 is reproduced below for the convenience of the Examiner:

> [0010] A number of techniques used to reduce exposure include minimizing the time of exposure of personnel, maintaining distance between personnel and the source of radiation and shielding personnel from the source of

> radiation. In general, the radiopharmaceuticals are typically delivered to a nuclear medicine facility from another facility equipped with a cyclotron in, for example, a lead-shielded container. Often, the radiopharmaceutical is manually drawn from such containers into a shielded syringe. See, for example, U.S. Pat. No. 5,927,351 disclosing a drawing station for handling radiopharmaceuticals for use in syringes. Remote injection mechanisms can also be used to maintain distance between the operator and the radiopharmaceutical. See, for example, U.S. Pat. No. 5,514,071, disclosing an apparatus for remotely administering radioactive material from a lead encapsulated syringe.

The only disclosure of "tracer" in Reilly '463 is in paragraph 8 below:

> Most PET radionuclides have short half-lives. Under proper injection procedures, these radionuclides can be safely administered to a patient in the form a labeled substrate, ligand, drug, antibody, neurotransmitter or other compound normally processed or used by the body (for example, glucose) that acts as a tracer of specific physiological and biological processes.

However, even paragraph 8 of Reilly '463 does not disclose "chemical synthesizer" or much less a "chemical synthesizer operably coupled to the radioisotope producer" as claim 16 requires. Thus, Reilly '463 does not disclose all elements required by claim 16. Therefore, applicant requests that the rejection of claim 16 under 35 U.S.C. 103(a) be withdrawn.

Please also see Applicants comments above in relation to claim 1 on the 1) missing elements in the references and 2) reason to combine 3) hindsight bias and 4) prima facie case of obviousness in regards to the absent resolution of the level of ordinary skill in the pertinent art. Applicant requests that the rejection of claim 16 under 35 U.S.C. 103(a) be withdrawn.

Per claim 17: Please see Applicant's comments above in regards to claim 2.

Per claim 19: Please see Applicant's comments above in regards to claim 5.

Per claim 23: Please see Applicant's comments above in regards to claim 11.

Per claim 30: Please see Applicant's comments above in regards to claim 5.

Per claim 40: Please see Applicant's comments above in regards to claim 1.

Per claim 41: Claim 41 requires "local area network is further operably coupled to a cyclotron…" However, neither Reilly '463 nor Hamedeh '188 disclose the "coupled" aspect between the "cyclotron" and the "local area network." Thus, Applicant requests withdrawal of the rejection of claim 41 under 35 U.S.C. 103(a).

Per claim 45: Please see Applicant's comments above in regards to claims 1 and 16.

Per claim 46: Please see Applicant's comments above in regards to claim 41.

Rejection of claims 7, 21, 26, 27, 28, 37, 42, 47 & 57 under 35 U.S.C. 103(a)

Claims 7, 21, 26, 27, 28, 37, 42, 47 & 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly '463 et al. (US Patent Application No. 200310004463 A1) and in view of Hamadeh 'l88 et al. (US Patent Application No. 200410088188 A1) and further in view of Critchlow '930 et al. (US Patent No. 6,520,930).

Please see comments above on 1) reason to combine 2) hindsight bias and 3) prima facie case of obviousness in regards to the absent resolution of the level of ordinary skill in the pertinent art. Applicant requests that the rejections of claims 7, 21, 26, 27, 28, 37, 42, 47 & 57 under 35 U.S.C. 103(a) be withdrawn.

Per claim 26: Please see Applicant's comments above in regards to claims 1, 2 and 16.

Per claim 27: Please see Applicant's comments above in regards to claim 2.

Rejection of claims 9, 12-13, 22, 24, 35, 36, 38, 43, 49-51, 54-56, 58, 61-63, 65-68, 70-77, 79 & 80 under 35 U.S.C. 103(a)

Claims 9, 12-13, 22, 24, 35, 36, 38, 43, 49-51, 54-56, 58, 61-63, 65-68, 70-77, 79 & 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly '463 et al. (US Patent Application No. 200310004463 A1) and in view of Hamadeh '188 et al. (US Patent Application No. 200410088188 A1) and further in view of Tamaki '1989 (Tamaki, et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989).

Please see comments above on 1) reason to combine 2) hindsight bias and 3) prima facie case of obviousness in regards to the absent resolution of the level of ordinary skill in the pertinent art. Applicant requests that the rejections of claims 9, 12-13, 22, 24, 35, 36, 38, 43, 49-51, 54-56, 58, 61-63, 65-68, 70-77, 79 & 80 under 35 U.S.C. 103(a) be withdrawn.

Per claim 12: Claim 12 requires "a control system operably coupled to the local area network." However, neither Reilly '463 nor Hamedeh '188 disclose the "coupled" aspect between the "control system" and the "local area network."

In addition, claim 12 requires an "injector system being operably coupled to the local area network." However, neither Reilly '463 nor Hamedeh '188 disclose the "coupled" aspect between the "injector system" and the "local area network."

Furthermore, claim 12 requires "a physiologic monitoring system operably coupled to the injector system." Again, neither Reilly '463 nor Hamedeh '188 disclose the "coupled" aspect between the "injector system" and the "physiologic monitoring system."

Per claim 13: The Office Action asserts that Reilly '463 paragraph 64 discloses "the amount of each individual dose is calculated based on …the projected time of injection into a living subject and high level descriptors of the living subject." Paragraph 64 of Reilly '463 does not disclose such requirements. For the convenience of the Examiner, paragraph 64 is provided as follows:

> [0064] In the case of injection of a radiopharmaceutical, positioning a pressurizing unit or chamber such as syringe 60 within dose calibrating unit 200 such as the Capintec CRC-15PET dose calibrator available from Capintec, Inc. of Ramsey, N.J., which measures the total radiation of the volume of radiopharmaceutical enclosed within the pressurizing chamber, shields administering personnel from radiation and enables delivery of a known volume of the radiopharmaceutical having a known radiation level (as measured directly by dose calibrating unit 200). The accurate control of injection volume and flow rate provided by powered injector 70 enables automatic injection of a calculated volume of fluid (using for example processing unit 71 of injector 70) that will provide the level of radiation necessary, for example, for a PET or SPECT image given the measured radiation of the total volume of radiopharmaceutical contained within syringe 60 provided by dose calibration unit 200. Thus, it is no longer necessary to calculate and wait for the precise moment in time when radioactive decay has brought the level of radiation of a volume of radiopharmaceutical to the desired level, thereby saving time and reducing the complexity of the injection procedure.

Thus, we can see that Reilly '463 paragraph 64 does not disclose the required matter of claim 13.

Teaches Away: On the contrary, Reilly '463 paragraph 64 teaches against "the amount of each individual dose is calculated based on …the projected time of injection into a living subject."

MPEP 2144.05.III states "A prima facie case of obviousness may also be

rebutted by showing that the art, in any material respect, teaches away from the claimed invention. In re Geisler, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997)" and MPEP 2145 X.D.2 states "It is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)."

Reilly '463 paragraph 64 states "Thus, it is no longer necessary to calculate and wait for the precise moment in time when radioactive decay has brought the level of radiation of a volume of radiopharmaceutical to the desired level, thereby saving time and reducing the complexity of the injection procedure." [Emphasis added.] This passage of Reilly '463 paragraph 64 teaches away from the requirements of claim 13, contrary to the instruction of the MPEP. Thus, applicant requests that the rejection of claim 13 under 35 U.S.C. 103(a) be withdrawn.

Per claim 24: Please see Applicant's comments above in regards to claim 12.

Per claim 35: Please see Applicant's comments above in regards to claims 1, 2 and 16.

Per claim 36: Please see Applicant's comments above in regards to claim 5.

Per claim 38: Please see Applicant's comments above in regards to claim 12.

Per claim 43: Please see Applicant's comments above in regards to claim 12.

Per claim 51: Please see Applicant's comments above in regards to claim 12.

Per claim 54: Please see Applicant's comments above in regards to claim 16.

Per claim 55: Please see Applicant's comments above in regards to claims 1, 2, 12 and 16.

Per claim 56: Please see Applicant's comments above in regards to claim 41.

Per claim 58: Please see Applicant's comments above in regards to claim 13.

Per claim 61: Please see Applicant's comments above in regards to claims 1, 2, 12 and 16.

Per claim 62: Please see Applicant's comments above in regards to claim 41.

Per claim 65: Please see Applicant's comments above in regards to claims 1, 2, 12 and 16.

Per claim 66: Please see Applicant's comments above in regards to claim 12.

Per claim 68: Please see Applicant's comments above in regards to claim 13.

Per claim 70: The Office Action asserts that Figure 1A, element 100 (catheter) and 60 (syringe) discloses "a positron emission tomography scanner operably coupled to the physiologic monitor and the injector." Paragraph 4 follows below for the convenience of the Examiner:

> [0004] Examples of use of a radiopharmaceutical include positron emission tomography (PET) and single-photon emission computerized tomography (SPECT), which are noninvasive, three-dimensional, imaging procedures that provide information regarding physiological and biochemical processes in patients. The first step in producing PET images or SPECT images of, for example, the brain or another organ, is to inject the patient with a dose of the radiopharmaceutical. The radiopharmaceutical is generally a radioactive substance that can be absorbed by certain cells in the brain or other organ, concentrating it there. For example, fluorodeoxyglucose (FDG) is a normal molecule of glucose, the basic energy fuel of cells, to which is attached a radionuclide or radioactive fluor. The radionuclide is produced in a cyclotron equipped with a unit to synthesize the FDG molecule.

Paragraph 4 discloses the "imaging procedure" of "positron emission tomography (PET)." However, that is not disclosure of "a positron emission tomography scanner" as required by claim 70.

Furthermore, claim 70 requires "a physiologic monitoring system operably coupled to the injector system." Again, neither Reilly '463 nor Hamedeh '188 disclose the "coupled" aspect between the "injector system" and the "physiologic

monitoring system."

Thus, applicant requests that the rejection of claim 70 under 35 U.S.C. 103(a) be withdrawn.

Per claim 75: Please see Applicant's comments above in regards to claim 1.

Per claim 76: Please see Applicant's comments above in regards to claim 1.

Rejection of claims 33 & 32 under 35 U.S.C. 103(a)

Claims 33 & 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly '463 et al. (US Patent Application No. 200310004463 A1) and in view of Hamadeh '188 et al. (US Patent Application No. 200410088188 A1), in view of Critchlow '930 et al. (US Patent No. 6,520,930 B2) and further in view of Tamaki '1989 (Tamaki, et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989).

Please see comments above on 1) reason to combine 2) hindsight bias and 3) prima facie case of obviousness in regards to the absent resolution of the level of ordinary skill in the pertinent art. Applicant requests that the rejections of claims 33 & 32 under 35 U.S.C. 103(a) be withdrawn.

Per claim 33: Please see Applicant's comments above in regards to claims 1, 2, 16 and 70.

Rejection of claims 14, 25, 34, 39, 44, 52, 53, 59, 60, 64, 69 & 78 under 35

U.S.C. 103(a)

Claims 14, 25, 34, 39, 44, 52, 53, 59, 60, 64, 69 & 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly '463 et al. (US Patent Application No. 200310004463 A1), in view of Hamadeh '188 et al. (US Patent Application No. 200410088188 A1), in view of Kroll '869 et al. (US Patent Application No. 20050288869 A1) and further in view of Tamaki '1989 (Tamaki, et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989).

Please see comments above on 1) reason to combine 2) hindsight bias and 3) prima facie case of obviousness in regards to the absent resolution of the level of ordinary skill in the pertinent art. Applicant requests that the rejections of claims 14, 25, 34, 39, 44, 52, 53, 59, 60, 64, 69 & 78 under 35 U.S.C. 103(a) be withdrawn.

Hindsight

The factfinder must remain aware of distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. See KSR Int'l Co. v. Teleflex Inc., citing Graham v. John Deere, 383 U.S., at 36. Moreover "[d]etermination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention..." ATD Corp. v. Lydall, Inc., 159 F.3d 534, 48 USPQ2d 1321 (Fed. Cir. 1998), see also KSR Int'l Co. v. Teleflex Inc., 550 U.S. ___ (2007), citing Monroe Auto Equipment Co. v. Heckethorn Mfg & Supply Co., 332 F.2d 406, 412 (CA6 1964)) (warning against a "temptation to read into the prior art the teachings of the invention in issue"). Hindsight must be avoided. In re Bond, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990).

In Ex Parte Rinkevich et al. (BPAI 2007-1317), the board cited KSR in reasoning that a skilled person would not look to a second patent to solve a problem already solved by a first patent (and by the patentee). The board wrote:

> "In the instant case, we conclude that a person of ordinary skill in the art having common sense at the time of the invention would not have reasonably looked to Wu to solve a problem already solved by Savill. Therefore, we agree with Appellants that the Examiner has impermissibly used the instant claims as a guide or roadmap in formulating the rejection."

In regards to the rejections under 35 U.S.C. 103(a) over Reilly '463 et al. (US Patent Application No. 200310004463 A1), in view of Hamadeh '188 et al. (US Patent Application No. 200410088188 A1), in view of Kroll '869 et al. (US Patent Application No. 20050288869 A1) and further in view of Tamaki '1989, and Kroll '869 solve the same problems in dosage of radiopharmaceuticals. For example, Reilly '463 states that conventional systems have problems with "administration of a proper dosage to a patient" of radiopharmaceuticals (paragraph 13) and that "[i]t is thus very desirable to develop devices, systems and methods through which toxic or hazardous pharmaceuticals (for example, radiopharmaceuticals) can be administered in controlled manner to enhance their effectiveness and patient safety, while reducing exposure of administering personnel to such hazardous pharmaceuticals." (paragraph 16).

While Kroll '869 states that conventional systems have problems with "optimally effective administered activity of the radiopharmaceutical for any given radiopharmaceutical" (paragraph 4), "[o]verdosing with the radiopharmaceutical may have dire consequences" "underdosing" and "repeat dosing" (paragraph 5).

As shown above, both Reilly '463 and Kroll '869 address the same problem of dosage of radiopharmaceuticals.

In this case, applicants respectfully suggest a person of ordinary skill in the art at the time of the invention would not have reasonably looked to Kroll '869 to solve the problems already solved by Reilly '463. Therefore, the Examiner has impermissibly used the instant claims as a guide or roadmap in hindsight to formulate the rejection using ver Reilly '463 et al. (US Patent Application No. 200310004463 A1), in view of Hamadeh '188 et al. (US Patent Application No. 200410088188 A1), in view of Kroll '869 et al. (US Patent Application No. 20050288869 A1) and further in view of Tamaki '1989 under 35 U.S.C. 103(a).

Thus, Applicants respectfully submit that the obviousness rejection of claims 14, 25, 34, 39, 44, 52, 53, 59, 60, 64, 69 & 78 was improper, and that claims 14, 25, 34, 39, 44, 52, 53, 59, 60, 64, 69 & 78 are allowable.

Rejection of claims 81-83 under 35 U.S.C. 103(a)

Claims 81-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly '463 et al. (US Patent Application No. 200310004463 A1), in view of Hamadeh 'l88 et al. (US Patent Application No. 2004/0088188 A1), in view of Kroll '869 et al. (US Patent Application No. 2005/0288869 A1), and further in view of Tamaki '1989 (Tamaki, et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989).

The Office Action assert that "Haines '692" "teaches executable instructions capable of directing a processor to perform calculating a required radiotracer dose activity (Figure 5) and comparing a total activity available in the multidose portion of the radiotracer to the required radiotracer dose activity (Page 6, Para 0068)" and "teaches using a notification system to notify the user when consumables are low or out (Col. 8, Line 15-34)." (Office Action pages 37-38).

However, "Haines '692" is not a reference of record. Neither is the full patent

or publication number of "Haines '692" disclosed in the record. Thus, Applicant requests that the rejections of claims 81-83 under 35 U.S.C. 103(a) be withdrawn.

Rejection of claims 84 & 85 under 35 U.S.C. 103(a)

Claims 84 & 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly '463 et al. (US Patent Application No. 200310004463 A1), in view of Hamadeh '188 et al. (US Patent Application No. 2004/0088188 A1), and further in view of Tamaki '1989 (Tamaki, et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989).

Please see comments above on 1) reason to combine 2) hindsight bias and 3) prima facie case of obviousness in regards to the absent resolution of the level of ordinary skill in the pertinent art. Applicant requests that the rejections of claims 84 & 85 under 35 U.S.C. 103(a) be withdrawn.

The Office Action cites Tamaki '1989 (page 1303 left column) as disclosure of "introducing a pharmaceutical stress agent into the patient." However, a reading of Tamaki '1989 shows that the only "stress agent" that the disclosed in Tamaki '1989 is exercise. Nowhere does Tamaki '1989 disclose a "pharmaceutical stress agent." Claim 84 is allowable on this one point alone. Thus, Applicant requests that the rejections of claims 81-83 under 35 U.S.C. 103(a) be withdrawn.

Nonetheless, Applicant has amended claims 84-85 to require further aspects that are not disclosed by the references of record. The amendments are supported by FIG. 1 and FIG. 4.

Applicant believes that claims 1-85 are allowable. If any issues remain that prevent issuance of this application, the Examiner is urged to contact the undersigned attorney Michael G. Smith at 202-595-1444 x2.

Respectfully Submitted,

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By: Michael G. Smith
45,368
Ivey, Smith and Ramirez
1250 Connecticut Ave NW,
#200
Washington, D.C. 20036-2603
(202) 595-1444 x2